
Medicare's End Stage Renal Disease Program

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Perhaps no other Federal Government program can lay claim to have saved as many lives as the Medicare end stage renal disease (ESRD) program. Since its inception in 1973, as a result of the Social Security Amendments of 1972 (Public Law 92-603, section 299I), over 1 million persons have received life-saving renal replacement therapy under this program. Prior to the enactment of this legislation, treatment was limited to a very few patients due to its extremely high cost and the limited number of dialysis machines. In the 1960s, it was not uncommon for hospitals that had dialysis machines to appoint special committees to review applicants for dialysis and decide who should receive treatment, the others were left to die of renal failure. Public Law 92-603 removed this odious task from the nephrology community. A person with ESRD is entitled to Medicare if he/she is fully or currently insured for benefits under Social Security, or is a spouse or dependent of an insured person. Consequently, entitlement is less than universal, with 92 percent of all persons with ESRD qualifying for Medicare coverage.

TREATMENTS

There are two basic treatments available to persons with ESRD—dialysis and transplantation. The most common form of dialysis is hemodialysis—the circulation of the body's blood through a machine that cleans the blood of toxins. The first artificial kidney machine was developed in the early

1940s in Holland. These machines could not maintain life for long because repeated treatments were not possible due to the lack of a means of repeatedly gaining access to the blood stream. The problem was partially solved in 1960, when a subcutaneous cannulae-and-shunt apparatus was developed that permitted the repeated access of patients to hemodialysis. Currently, the standard practice of hemodialysis are treatments 3 times a week for 3 to 4 hours at a time.¹ Although hemodialysis can be performed at home, the great majority of patients dialyze at one of nearly 4,000 facilities providing this service.

Another form of dialysis, done primarily at home, is peritoneal dialysis, of which there are three types. Continuous ambulatory peritoneal dialysis (CAPD) is the most common type of peritoneal dialysis. It needs no machine. With CAPD, the blood is continuously being cleaned. A solution called the dialysate, passes from a plastic bag through a catheter into the abdomen. The dialysate stays in the abdomen with the catheter sealed. After several hours, the person using CAPD drains the solution back into a disposable bag. Then the person refills the abdomen with fresh solution through the same catheter, to begin the cleaning process again. Continuous cyclic peritoneal dialysis (CCPD) is a form of peritoneal dialysis that uses a machine. This machine automatically fills and drains the dialysate from the abdomen. A typical CCPD schedule involves three to five exchanges during the night while the per-

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¹ Currently, a number of dialysis providers are experimenting with more frequent dialysis (5 or 6 times per week, but of shorter duration, 1½ hours).

son sleeps. During the day, the person using CCPD performs one exchange that lasts the entire day. Nocturnal intermittent peritoneal dialysis (NIPD) is a machine-aided form of peritoneal dialysis. NIPD differs from CCPD in that six or more exchanges take place during the night, and the NIPD patient does not perform an exchange during the day. As of 1998, 89 percent of patients used hemodialysis, 6 percent used CAPD, and 5 percent used either CCPD or NIPD (Health Care Financing Administration, 1999a).

Transplantation dates back to 1956, when the first successful transplant was performed on identical twins. Successful transplants of kidneys from cadavers began in the early 1960s. A successful transplant relieves the patient of the necessity of dialysis and usually improves the quality of life. However, the patient must take immunosuppressive drugs for the rest of his/her life to prevent the body's immune system from rejecting the transplanted kidney. At the time of the initiation of the program in 1973, transplantation was considered to be a bridge therapy between periods of dialysis (Kasiske et al., 2000) because of high graft failure rates. However, due to greatly improved graft success rates, transplantation is generally considered to be the optimal therapy for most patients.

LEGISLATIVE CHANGES

Although the basic entitlement provisions of the 1972 legislation remain in place, there have been a number of legislative changes to the program over the years. The first was the ESRD Program Amendment (Public Law 95-292) passed in 1978. The original legislation had limited Medicare entitlement to 1 year following a successful transplant. This was extended in 1978 to 3 years, although many success-

ful transplant recipients remain on Medicare after this point because they qualify under the disabled or age provisions of Medicare. In addition, the 1978 provisions increased coverage of kidney acquisition costs and provided for more complete coverage of home dialysis costs. The Omnibus Budget Reconciliation Act (OBRA) of 1981 included the Medicare secondary payer (MSP) provision. MSP provides that, if a beneficiary has insurance other than Medicare, then the other insurer is responsible for medical costs prior to Medicare. OBRA 1981 set the MSP period at 12 months from the date of Medicare entitlement. Subsequently, it was raised to 18 months in 1990, and then 30 months in 1997. In addition, OBRA 1981 resulted in the development of the composite rate payment system for dialysis. Originally, dialysis was paid for on a cost basis with an upper screen limit of \$138 per treatment. (The screen was \$150 in the initial year, with \$12 allowed for physician services.) This included an exceptions process which results in even higher payment levels, primarily to hospital-based facilities. Beginning in 1983, when the composite rate became effective, payment levels for hospital-based and freestanding facilities were roughly \$131 and \$127, respectively. These rates remained largely unchanged until the Balanced Budget Refinement Act of 1999, which increased the rates by 1.2 percent in both 2000 and 2001.

OBRA 1986 mandated the creation of a national registry for ESRD, which resulted in the United States Renal Data System (USRDS). The USRDS is a cooperative project between HCFA and the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDKD). NIDDKD provides most of the funding for the USRDS. HCFA provides extensive data from the ESRD Program Management and Medical Information System as well as fund-

ing for the economic studies portion of the USRDS. Since its first annual report in 1989, the USRDS has been the primary source of clinical, epidemiological, and economic information on ESRD in the United States.

The Balanced Budget Act of 1997 (Section 4558), mandated that HCFA develop a method to measure and report on the quality of renal dialysis services under Medicare. The development of quality of care measures did not take place in a vacuum. The renal community, including provider and patient groups (USRDS, NIDDKD, National Kidney Foundation, and HCFA) have a long history of working together on quality initiatives. For example, since 1993, HCFA has conducted an annual survey of quality measures (Health Care Financing Administration, 1999b). In 1997, the National Kidney Foundation published the Dialysis Outcomes Quality Initiative, a set of guidelines for adequacy of hemodialysis, adequacy of peritoneal dialysis, vascular access procedures, and treatment of anemia (National Kidney Foundation, 1997). Based on these previous efforts, HCFA has developed a set of 16 performance measures. It is anticipated that these measures, which will be applied at the individual dialysis facility level, will be published on the HCFA website (<http://www.hcfa.gov>) by late 2000.

TRENDS IN BENEFICIARY CHARACTERISTICS

As previously noted, prior to the enactment of the legislation creating the ESRD program, there were severe limits on the number of persons who received treatment. As a result, the ESRD patient profile prior to 1973 was much different than it became under Medicare. In 1967, the dialysis population was predominantly male (75 percent), overwhelmingly white per-

sons (91 percent), and very young (7 percent over the age of 55). By 1978, there were equal proportions of males and females, black persons accounted for 35 percent of patients, and 46 percent of the dialysis population were over the age of 55 (Evans, Blagg, and Bryan, 1981). In addition to providing access to treatment more in line with the underlying renal disease burden, Medicare coverage greatly expanded the number of patients receiving treatment. Early estimates of the program were that as many as 10,000 new patients would initiate therapy each year and that the program would level out at about 35,000 beneficiaries (Klar, 1972). Program enrollment has far outstripped initial estimates. Program incidence (number of new patients each year) was over 14,000 in 1978, approximately 32,000 in 1986, approximately 65,000 in 1994, and reached 75,000 in 1998—over 7 times the initial estimates. The reasons for this increase are not well understood and are generally referred to under the designation of expanded acceptance criteria. Expanded acceptance treatment criteria are evident in two major areas—age and diabetes. In 1978 one-fourth of newly treated patients were 65 years or over. By 1998, well over one-half of new patients were 65 years or over at the time of renal failure. In the years before the Medicare ESRD program, diabetes was usually considered a contraindication to treatment. By 1978, persons whose renal failure was due to diabetes still accounted for only 10 percent of new patients. In 1998, 45 percent of new patients had renal failure due to diabetes. This expansion has occurred without specific design or intent. It appears that, as nephrologists and dialysis centers became more successful at treating these more fragile patients, referrals for treatment increased accordingly.

As previously noted, the two basic therapies are dialysis and transplantation. From the beginning of the program until the mid-1980s, there were rapid increases in both the number of transplants and in transplant success rates (Hariharan et al. 2000). As a result, the percent of patients with a functioning kidney transplant more than doubled, from 10 percent to 22 percent by 1986 (Eggers, 1988). Since 1986, growth in the number of transplants has slowed, largely because of the limitation in the number of donated cadaver kidneys. Much of the growth in the number of transplants in recent years is due to increasing numbers of living donor transplants. Living donors accounted for 20 percent of all kidney transplants in 1988 and 34 percent in 1998. Thus, despite the fact that transplant success rates are improving, the ever increasing dialysis population has offset these transplant gains. From 1986 to 1998, the percent of Medicare ESRD beneficiaries with a functioning graft has remained largely unchanged.

TRENDS IN PROGRAM EXPENDITURES

The original projections of annual program expenditures were quite low, having the program level out at about \$250 million (Klar, 1972).² The program has grown far beyond these initial estimates. By 1979, it reached \$1 billion, \$5 billion by 1990, and, by 1998, had grown to over \$12.3 billion. Despite this large increase in total expenditures, compared with the rest of the Medicare program, ESRD has been fairly successful at restraining per capita costs (Eggers, 2000). Enrollment increases account for much of the unexpected increase. Total ESRD Medicare enroll-

² It is not clear whether the original estimates included Medicare expenditures not directly related to dialysis and transplantation. Costs for other covered Medicare services account for about one-half of expenditures on behalf of ESRD patients.

ment in 1998 was almost 300,000, accounting for 0.8 percent of total Medicare enrollment, compared with 0.1 percent of Medicare enrollment in 1974. In addition, because expenditures increase with age and are greater for beneficiaries who are diabetic, the increasing percentage of patients who are elderly and/or diabetic has increased program expenditures by about 21 percent over the impact of enrollment increases alone.

In 1974, the average ESRD patient was 30 times as expensive as the average Medicare beneficiary. By 1998, the average ESRD patient was about 7.5 times as expensive as the average Medicare beneficiary. The reason for this is that during the 1970s and 1980s, when medical care inflation was usually in the double digits, two major parts of ESRD care, dialysis and physician care (known as the monthly capitation payment), remained largely unchanged. The dialysis payment rate (the composite rate), is lower in nominal terms in 1998 than it was in 1974. In inflation-adjusted terms, payment for dialysis is about one-third as great as it was in 1974.

TRENDS IN PROGRAM QUALITY OF CARE

Dialysis—The large decrease in inflation adjusted payment rates for dialysis has raised the question of how this has affected quality of care (Institute of Medicine, 1991, Health Care Financing Administration, 1989). There has been no evidence of decreased quality of care. Dialysis mortality rates have decreased in recent years (United States Renal Data System, 1999), from 28 percent in 1986 to 19 percent in 1996. In addition, the decreases in mortality have been greatest for persons with diabetes, among the most fragile of dialysis patients. Patient outcomes are improving in other areas as well. Healthy kidneys

produce the chemical erythropoietin, which stimulates the production of red blood cells. Thus, kidney failure often results in anemia as the body is unable to produce a sufficient supply of red blood cells. For a number of years, the only treatment of anemia was occasional blood transfusions. In 1989, the Food and Drug Administration approved the production of (and Medicare began payment for) a recombinant form of erythropoietin. Now, virtually all hemodialysis patients, and many CAPD patients receive erythropoietin. As a result, average hematocrit levels have increased. In 1993, only 46 percent of patients had a hematocrit above 30 percent. By 1998, this had increased to 83 percent (Health Care Financing Administration, 1999b).

Transplantation—The major problem in achieving a successful transplant is combating the body's natural immune system which attempts to reject the transplanted kidney graft. In the 1970s, the available drugs were somewhat limited. One-year graft survival rates for transplants from cadavers were about 50 percent. This success rate increased to about 70 percent in the 1980s. The introduction of cyclosporine in 1984 greatly increased the success of transplantation (Powe, Eggers, and Johnson, 1994), as has additional improvements in immunosuppression. As a result, by 1997, one-year graft survival rates had increased to 88 percent for cadaver grafts and 94 percent for recipients of living donor grafts. One-year patient survival rates are 94 percent and 98 percent for recipients of cadaver and living donor graft, respectively.

SUMMARY AND CONCLUSION

Medicare's ESRD program has largely achieved the original goal of providing access to life sustaining care for thousands

of persons who would not otherwise have received care. During its 27-year history, many legislative changes have been made to refine coverage and entitlement issues. Despite certain limitations on payments, improvements in quality have been made, both for dialysis patients and transplant patients.

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